

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
Rudolf MOSER et al. : Group Art Unit.: 4173
Serial No.: 10/562,200 : Examiner: STONE, Christopher R.
Filed: November 8, 2006 :
Title: STABLE PHARMACEUTICAL COMPOSITIONS OF
5,10-METHYLENE TETRAHYDROFOLATE

REPLY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

In response to the Office Action mailed on September 18, 2010, and further to the Notice of Appeal file on February 18, 2010, please amend the claims as follows and consider the remarks in view of the concurrently filed RCE.

The Office Action takes the position that all folates behave similarly and that a person skilled in the art could easily transform or even copy in a 1:1 manner existing knowledge from one specific folate to another one. That is by far not correct.

So, the stabilization of 5-formyltetrahydrofolic acid, particularly solutions thereof, cannot be compared with the stabilization of 5,10-methylenetetrahydrofolic acid solutions. Despite belonging to the same general class of compounds (folates) the two substances show properties which differ considerably. Amongst others their stability behaviour and their paths of decomposition are totally different. This difference is widely known and accepted by people working in this field, and as such would be taken into consideration.

One remarkable example for the different behavior is that compositions of 5,10-methylenetetrahydrofolic acid can be stabilized according to the claimed invention by using citrate. However no stabilization of 5,10-methylenetetrahydrofolic acid occurs when citrate is replaced by acetate, oxalate, maleate or salts of other acids. On the other hand, e.g., WO 95/26963, attributes acetate and citrate as having a comparable effect on the stabilization of 5-formyltetrahydrofolic acid.